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| **Section I: Instructions** | | | | |
| **1.** Use this form to help determine whether FDA Investigational New Drug (IND) Application regulations at [21 CFR 312](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=d0d8e65f5505f73466368b6041de1b55&mc=true&n=pt21.5.312&r=PART&ty=HTML) apply to the research project. It is recommended to complete this checklist during protocol development. | | | | |
| **2.** Complete this form electronically and include it with your OSF Research Application when the research involves off-label use of an approved \*drug. | | | | |
| *\*Drug* includes drugs, biologics, and other compounds other than food that are intended to diagnose, treat, mitigate, cure, or prevent disease, or otherwise affect the structure or function of the body. | | | | |
| **3.** In using the checklist to determine if an IND is needed for your research, also consider the following: | | | | |
| **a.** Single-dose bioequivalence studies of nonradioactive drugs intended to support generic drug development are generally not subject to IND regulations. | | | | |
| **b.** Regardless of whether the proposed investigation requires an IND, the study must comply with the FDA regulations on human subjects protections and informed consent ([21 CFR 50](https://www.ecfr.gov/cgi-bin/text-idx?SID=fea5392a1f0d3fd048f20cb8e194b798&mc=true&node=pt21.1.50&rgn=div5)) and IRB oversight ([21 CFR 56](https://www.ecfr.gov/cgi-bin/text-idx?SID=fea5392a1f0d3fd048f20cb8e194b798&mc=true&node=pt21.1.56&rgn=div5)), and may also be subject to HHS regulations on the Protection of Human Subjects ([45 CFR 46](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=7&SID=20bb14fe18099b9e7a9692428b0b36f9&ty=HTML&h=L&mc=true&n=pt45.1.46&r=PART)). | | | | |
| **c.** Research projects may not promote the drug ([21 CFR 312.7](https://www.ecfr.gov/cgi-bin/text-idx?SID=ccd8b74812815f59ab9492f36f2e0df6&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_17)). | | | | |
| **d.** Studies conducted under an IND may not charge for the investigational drug, except in certain circumstances with written FDA approval ([21 CFR 312.8](https://www.ecfr.gov/cgi-bin/text-idx?SID=ccd8b74812815f59ab9492f36f2e0df6&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_18)). | | | | |
| **e.** Other regulations such as those implementing the [HIPAA Privacy Rule](https://www.hhs.gov/hipaa/for-professionals/privacy/index.html?language=es), the [Medicare Clinical Trials Policy](https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/clinicaltrialpolicies/), and Electronic Data Regulations ([21 CFR 11](https://www.ecfr.gov/cgi-bin/text-idx?SID=30daaab3d80848693a1baf1353cd23e0&mc=true&node=pt21.1.11&rgn=div5)) may also apply. | | | | |
| **f.** If the project involves a device, FDA device regulations may apply ([21 CFR 812](https://www.ecfr.gov/cgi-bin/text-idx?SID=a21c0d1d1486ca875939925ce3447681&mc=true&node=pt21.8.812&rgn=div5)). | | | | |
| **g.** Consult the [FDA guidance on INDs](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) for further details. | | | | |
| **Section II: General Information** | | | | |
| **1. Principal Investigator Name:** | | | | |
| **2. Project/Protocol Title:** | | | | |
| **Section III: IND Applicability** | | | | |
| **1. Does the project involve administration of a drug to humans?** | | | | |
| Yes | | | | |
| No **>** STOP completing Section III here; the research does not require an IND. Proceed to Section IV. | | | | |
| **2. Is the research a \*clinical investigation?** | | | | |
| *\*Clinical investigation* is any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this document, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice*.* | | | | |
| Yes | | | | |
| No **>** STOP completing Section III here; the research does not require an IND. Proceed to Section IV. | | | | |
| **3. Is the drug lawfully marketed in the U.S. as a drug?** | | | | |
| Yes | | | | |
| No **>** STOP completing Section III here; the research requires an IND. Proceed to Section IV. | | | | |
| **4. Is there an intention to submit the data collected in the study to FDA as a well-controlled study in support of a new indication or any other significant change in labeling for the drug?** | | | | |
| Yes **>** STOP completing Section III here; the research requires an IND. Proceed to Section IV. | | | | |
| No **>** Explain: | | | | |
| **5. Is the information collected in the study intended to support any significant change in the advertising for a lawfully marketed prescription drug product?** | | | | |
| Yes **>** STOP completing Section III here; the research requires an IND. Proceed to Section IV. | | | | |
| No **>** Explain: | | | | |
| **6. Does the proposed route of administration *significantly* increase the risks, or decrease the acceptability of the risks, associated with the drug?** | | | | |
| Yes **>** STOP completing Section III here; the research requires an IND. Proceed to Section IV. | | | | |
| No **>** Explain: | | | | |
| **7. Does the proposed patient population *significantly* increase the risks, or decrease the acceptability of the risks, associated with the drug?** | | | | |
| Yes **>** STOP completing Section III here; the research requires an IND. Proceed to Section IV. | | | | |
| No **>** Explain: | | | | |
| **8. Does the proposed dosage level *significantly* increase the risks, or decrease the acceptability of the risks, associated with the drug?** | | | | |
| Yes **>** STOP completing Section III here; the research requires an IND. Proceed to Section IV. | | | | |
| No **>** Explain: | | | | |
| **9. Does the study involve any other factor that *significantly* increases the risks, or decreases the acceptability of the risks, associated with the drug?** | | | | |
| Yes **>** The research requires an IND. Proceed to Section IV. | | | | |
| No **>** Explain: | | | | |
| **Section IV: Final Determination** | | | | |
| **1. If the responses to questions III.4 through III.9 are all “No”, and you are conducting the investigation in compliance with the requirements for review by an IRB (**[**21 CFR 56**](https://www.ecfr.gov/cgi-bin/text-idx?SID=fea5392a1f0d3fd048f20cb8e194b798&mc=true&node=pt21.1.56&rgn=div5)**), informed consent (**[**21 CFR 50**](https://www.ecfr.gov/cgi-bin/text-idx?SID=fea5392a1f0d3fd048f20cb8e194b798&mc=true&node=pt21.1.50&rgn=div5)**), and the promotion and sale of investigational drugs (**[**21 CFR 312.7**](https://www.ecfr.gov/cgi-bin/text-idx?SID=ccd8b74812815f59ab9492f36f2e0df6&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_17)**), then the IND exemption requirements are met.** | | | | |
| **a. The final determination for this research is (choose one):** | | | | |
| The research does require an IND **>** Proceed with the [FDA IND application process](https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm). | | | | |
| The research does not require an IND **>** Complete **i.**: | | | | |
| **i. My signature below confirms I have evaluated the above named study in light of** [**21 USC § 355(i)**](https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec355.pdf)**, the regulations in** [**21 CFR Part 312**](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title21/21cfr312_main_02.tpl)**, and** [**related guidance**](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)**, and determined that the study qualifies for exemption from the IND requirement in accordance with the cited requirements and guidance.** | | | | |
|  |  |  |  |  |
|  | Principal Investigator Signature |  | Date |  |